

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/535,597	DENYER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	COLIN STUART	3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to pre-brief conference request 3/22/10.
2. ☒ The allowed claim(s) is/are 1-27.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>5/10/10</u>.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|---|

/COLIN STUART/  
Examiner, Art Unit 3771

### **DETAILED ACTION**

1. This action is in response to the pre-appeal brief request filed 3/22/10. As discussed in the conference and explained below, the application with the examiner's amendment also discussed below is in condition for allowance of claims 1-27.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Timothy Nathan on 5/10/10.

#### **The application has been amended as follows:**

1. (Currently Amended) A method of generating signals in a drug delivering apparatus through which a person inhales to generate an inhaled airstream, comprising the steps of:

detecting the commencement of inhalation via a sensor;

signalling to the person to cease inhalation after a pre-set period of time has elapsed from the detection of the commencement of breathing;

detecting, via the sensor, a time the person takes to stop inhaling after being signalled; and

adjusting the pre-set period of time for subsequent inhalations depending on the time the person takes to stop inhaling after being signalled.

### **REASONS FOR ALLOWANCE**

3. The following is an examiner's statement of reasons for allowance: when read in light of the limitations of the claimed drug delivery apparatus/method, the prior art of record by itself or in combination does not disclose the specific functional steps as recited in claims 1 or 21 such that a drug delivery apparatus functions to detecting, with a sensor, the commencement of inhalation of a user, signals the user to cease inhalation after a pre-set period of time, and detect, via the sensor, a time the person takes to stop inhaling after being signaled, and to adjust the pre-set period of time for subsequent inhalations depending on the time the person takes to stop inhaling.

The closest prior art references are: Edgar et al. (4,677,975), Schuster et al. (5,906,202), Mishelevich et al. (5,363,842), and Crockford et al. (2003/0205229) which all relate to drug deliver devices/methods.

The prior art of record does not disclose the specific functional limitations of the claimed drug delivery device/method such that a drug delivery apparatus functions to detecting, with a sensor, the commencement of inhalation of a user, signals the user to cease inhalation after a pre-set period of time, and detect, via the sensor, a time the person takes to stop inhaling after being signaled, and to adjust the pre-set period of time for subsequent inhalations depending on the time the person takes to stop inhaling. Although the combined prior art may teach similar structural elements as the claimed

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device; however, there is no motivation or obviousness to configure the structural elements to perform the above discussed functional limitations.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/

Examiner, Art Unit 3771

/Steven O. Douglas/

Primary Examiner, Art Unit 3771